

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant	:	Isamu Koyama et al.)	Confirmation No.: 9395
)	
Serial No.	:	10/594,720)	
)	Examiner: Julie Ann Szpira
Filed	:	September 29, 2006)	
)	Art Unit: 3731
For	:	DEVICE FOR SUPPORTING)	
		INSERTION OF MEDICAL)	
		INSTRUMENT INTO HUMAN)	
		BODY)	Date: April 8, 2010

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Appellant hereby requests formal review of the December 8, 2009, final office action. This paper is being filed concurrently with a Notice of Appeal and the requisite fee, as required in the guidelines for the New Pre-Appeal Brief Conference Pilot Program published in the July 12, 2005, Official Gazette Notice.

Claims 1, 2, 4-7 and 10 currently are pending and stand finally rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Fukuda et al. (U.S. Patent No. 3,871,358; hereinafter, “the ‘358 patent”) in view of Turnbull et al. (U.S. Patent No. 5,996,582, hereinafter, the ‘582 patent), and further in view of Gomez (U.S. Patent No. 6,053,166, hereinafter, the ‘166 patent). This the rejection is in error at least because the Office improperly overlooks structural features recited in independent claims 1 and 2 related to the guiding member element and the tubular member when either their engagement sections are engaged or their alignment marks are aligned with one another, as pointed out in the remarks starting at the middle of page 7 of Appellants’ response filed on August 12, 2009.

More specifically, the Office fails to properly consider the features of “when the guiding member engagement section is engaged with the tubular member engagement section, or when the guiding member alignment mark and the tubular member alignment

mark are aligned with each other, the digestive organ end of the guiding member is generally coincident with the digestive organ end of the tubular member.” These features of claims 1 and 2 are not described in, or otherwise suggested by the ‘358 patent, as correctly acknowledged by the Office on page 3 of the final Office Action. The Office, instead, relies on the ‘582 and the ‘166 patents for allegedly teaching claimed features related to the guiding member that are missing from the ‘358 patent. However, the ‘582 patent and the ‘166 patent fail to make up for these acknowledged deficiencies.

The ‘582 patent does not mention anything about ends of a guiding member and tubular member being coincident when engaged or aligned, as claimed. To the contrary, when the stop 22 and machine end 13 of the Turnbull assembly are engaged, the shield plate 23 at the end of the rod 21 extends well beyond the end 12 of the tubular member 10. In fact, the purpose the tube 10 is to provide a way to insert an expandable shield member into the airway of a subject, and the shield can only expand and function as intended when rod 21 is inserted so the shield plate at the end extends past the end 12 (see, column 3, lines 12-20). Thus, the ‘582 patent actually appears to *teach away* from the claimed structural features of coincident ends of the tubular member and guiding member when the engagement sections are engaged.

The ‘166 patent is relied on for allegedly teaching the claimed features related to alignment marks. However, the ‘166 patent does not describe, suggest or otherwise render obvious the inclusions of alignment marks on both a tubular member and a guiding member, much less the claimed features of digestive organ ends of these members being generally coincident when the marks are aligned with each other. Furthermore, the Office’s interpretation that the introduction segments 22, 26 and 30 (see, FIG. 4 and column 5) of the intubating assembly of the ‘166 patent are “alignment marks” is not believed reasonable when considering the plain meaning of this term as understood by one of ordinary skill in the art. Nor are the segments 22, 26 and 30 of the assembly described in the ‘166 patent relevant to claimed subject matter relating to alignment marks on a guiding member.

To establish a *prima facie* case of obviousness, the Office must consider all features recited in the claims. This consideration must show where the features are shown in applied prior art or otherwise provide an explanation why the claimed features as a whole would have been known or obvious. As pointed out above, the Office has failed to give proper

consideration to all the features of independent claims 1 and 2, and thus also to claims 4-7 and 10¹ depending from these claims. Accordingly, the rejection is believed to be improper.

Section 2143.03 of the MPEP requires the “consideration” of every claim feature in an obviousness determination. To render independent claims 1 and 2 unpatentable, however, the Office must do more than merely “consider” each and every feature of these claims. Instead, the asserted combination of the ‘358, ‘582 and ‘166 patents must also teach or suggest *each and every claim feature*. See, *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974) (emphasis added) (to establish *prima facie* obviousness of a claimed invention, all the claim features must be taught or suggested by the prior art). Further, the necessary presence of all claim features is axiomatic, since the Supreme Court has long held that obviousness is a question of law based on underlying factual inquiries, including ... ascertaining the differences between *the claimed invention* and the prior art. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) (emphasis added). Indeed, Appellants submit that this is why Section 904 of the MPEP instructs examiners to conduct a prior art search that covers “the invention *as described and claimed*.” (Emphasis added). Lastly, Appellants respectfully direct attention to MPEP § 2143, the instructions of which buttress the conclusion that obviousness requires at least a suggestion of all of the features of a claim, since the Supreme Court in *KSR Int’l v. Teleflex Inc.* stated that “there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR Int’l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) (*quoting In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)).

In sum, it remains well-settled law that obviousness requires at least a suggestion of all of the features in a claim. See *In re Wada and Murphy, citing CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) and *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)).

For at least these reasons, and in view of the arguments submitted in the Appellants’ response filed on August 12, 2009, which are incorporated herein by reference, withdrawal of the pending rejection of the claims is earnestly solicited.

¹ Upon review of the appealed claims, it has been discovered that claim 10 depends from claim 3, which was canceled in an amendment dated April 1, 2009. The dependency of claim 10 should have been amended so that claim 10 depends from claim 1. Should a decision on this request result in the allowance of claim 1, the Office is hereby granted permission to amend claim 10 so it depends from claim 1.

Further, while no fees are believed to be due, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-4525.

Respectfully submitted,

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